Ghaffar O, McCullagh S, et al. Randomized treatment trial in mild traumatic brain injury. J Psychosomatic Research 2006;61:153-160.

Design: Randomized clinical trial

Population/sample size/setting:

- 191 patients (124 men, 67 women, mean age 32) treated for mTBI at the University of Toronto
- Patients were recruited from two tertiary trauma centers after presenting with mTBI to two emergency departments and meeting the mTBI definition criteria of the American Congress of Rehabilitation Medicine; age eligibility was between 18 and 60
- Exclusion criteria were a major medical illness such as cardiac or cerebrovascular disease

Main outcome measures:

- Randomized to either a multidisciplinary TBI clinic (n=97) or to no treatment (n=94)
- Multidisciplinary clinic provided education in a standardized manner by an occupational therapist at each visit, and evaluation by two physicians
    - One physician was a neurorehabilitation specialist who focused on the physical symptoms (pain, headache, dizziness) and the other was a neuropsychiatrist who focused on depression, anxiety, and sleep
    - Sessions varied in frequency depending on clinical need from weekly to monthly or bimonthly (assuming the latter to be once every other month rather than twice per month)
- The control group had no contact with the study from the time of randomization until they were contacted 6 months after injury for a follow-up interview
- Several outcomes were compared between groups: postconcussive symptoms measured on the Rivermead Post-Concussion Disorder Questionnaire (RPCQ), psychosocial outcome measured on the Rivermead Follow-up Questionnaire (RFQ) , psychological distress on the 28-item General Health Questionnaire (GHQ) , and cognitive function on a battery of nine tests of attention, working memory, executive function, and psychomotor speed
- At the 6-month follow-up assessment, 86 patients in the rehabilitation group and 84 patients in the control group remained in the study; the outcome of the dropouts was unknown
    - However, only 67 patients in the rehabilitation group and 52 patients in the control group completed the cognitive and symptomatic follow-up evaluation in Table 2
- There was no difference between the groups on the RPCQ, the RFQ, or the GHQ measure of psychological distress
- Cognitive outcomes did not differ between groups on any of the nine tests of the neuropsychological battery

- 52 patients (30.8% of the entire sample) had a history of prior head injury; this group did not differ on any indices of TBI or on any outcome measure from the group with no prior history of TBI
- 39 patients (23% of the sample) reported a psychiatric history of anxiety or depressive disorders
    - Patients with and without a psychiatric history had the same indices of TBI severity and had the same scores on the cognitive function battery
    - Patients with a psychiatric history were more likely to have higher scores on the depression subscale of the GHQ and were more likely to report psychosocial difficulty on at least one item of the RFQ
    - When only patients with a psychiatric history were compared, the patients in the multidisciplinary rehabilitation group had less depression on the GHQ subscale than the patients in the control group
- Although 30% of the patients were involved in some kind of litigation, and they reported more post-concussive symptoms than non-litigants, there were no differences between these groups with respect to response to treatment, and litigation had no measurable effect on cognitive scores

Authors' conclusions:

- Routine follow-up treatment of all patients with mTBI does not appear to yield improvements in post-concussive symptoms or in cognitive function
- Follow-up of a subset of mTBI patients with a history of a psychiatric diagnosis is likely to yield positive results in decreasing depressive symptoms 6 months after the acute injury
- Many patients did not complete the cognitive tests, reflecting a reluctance to commit to the extra time demanded by neuropsychological testing

Comments:

- Table 2 displays results of measures of postconcussive symptomatology and the results of formal cognitive testing
    - It is plausible that many patients were reluctant to commit to the time required for a cognitive test battery, explaining why there were only 67 patients in the rehabilitation group and 52 in the control group
    - It is not clear that these were the numbers of patients who furnished data on their level of symptomatology, which would not require the same level of time commitment
    - Interpreting the reduced participation in the follow-up testing depends on whether the non-participation is related to the cognitive function of the patients
    - If patients who felt fully recovered were reluctant to commit the time for testing, then the patients who completed the testing would be more likely to be the patients who were experiencing cognitive symptoms
        - If this is the reason for the reduced participation, the comparisons in Table 2 may not be greatly biased, since the inclusion of fully recovered patients would have made the groups more equal

- The authors mention the lack of statistical adjustment for multiple comparison as a possible limitation of the study; however, this is more likely to be a source of concern when “statistically significant” results are reported, and is not likely to bias the comparisons in this study
- It appears that most of the patients in the rehabilitation group attended the follow-up sessions only every other month (though they could have attended more frequently), since the mean number of physician visits was only 3.3 over the 6 months of the study

Assessment: Adequate for evidence that routine scheduling of rehabilitative follow-up for mTBI is not likely to improve outcomes, and that follow-up is more likely to be productive if mTBI patients with a psychiatric history are selectively invited for follow-up